

112TH CONGRESS  
2D SESSION

# S. 2292

To promote accountability, transparency, innovation, efficiency, and timeliness  
at the Food and Drug Administration for America's patients.

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## IN THE SENATE OF THE UNITED STATES

APRIL 17, 2012

Mr. BURR (for himself and Mr. COBURN) introduced the following bill; which  
was read twice and referred to the Committee on Health, Education,  
Labor, and Pensions

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## A BILL

To promote accountability, transparency, innovation, effi-  
ciency, and timeliness at the Food and Drug Administra-  
tion for America's patients.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Promoting Account-  
5 ability, Transparency, Innovation, Efficiency, and Timeli-  
6 ness at FDA Act of 2012” or the “PATIENTS’ FDA  
7 Act”.

8 **SEC. 2. TABLE OF CONTENTS.**

9 The table of contents for this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.

## TITLE I—ENSURING GREATER TRANSPARENCY AND ACCOUNTABILITY IN FDA REGULATORY DECISIONMAKING

- Sec. 101. Advancing regulatory science to promote public health and innovation.
- Sec. 102. Reporting with respect to prescription drugs.
- Sec. 103. Reporting with respect to generic drugs.
- Sec. 104. Reporting with respect to biosimilars.
- Sec. 105. Documentation of regulatory decisions.
- Sec. 106. Review of regulations and guidance.
- Sec. 107. Leveraging information technology to fulfill FDA's public health mission.

## TITLE II—RECALIBRATING RISK-BENEFIT CONSIDERATIONS

- Sec. 201. Devices.
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## TITLE III—REDUCING UNNECESSARY DELAYS AND REGULATORY BURDENS

- Sec. 301. Optimizing global clinical trials.
- Sec. 302. Advancing American patients' timely access to innovative devices.
- Sec. 303. Ensuring legal sufficiency and consistency of FDA enforcement policies.

## TITLE IV—STRENGTHENING ADVISORY COMMITTEES FOR PATIENTS

- Sec. 401. Strengthening advisory committees for patients.

## TITLE V—MEDICAL DEVICE REGULATORY IMPROVEMENTS

### Subtitle A—Premarket Predictability

- Sec. 501. Tracking and review of applications for investigational device exemptions.
- Sec. 502. Investigational Device Exemptions.
- Sec. 503. Device submission acceptance criteria.
- Sec. 504. Transparency in clearance process.
- Sec. 505. Restoring regulatory certainty with respect to 510(k) reports required for certain modifications.
- Sec. 506. Meeting the device needs of individual patients.

### Subtitle B—FDA Renewing Efficiency From Outside Reviewer Management

- Sec. 511. Persons accredited to review reports under section 510(k) and make recommendations for initial classification.
- Sec. 512. Persons accredited to conduct inspections.

## TITLE VI—STRENGTHENING MANAGEMENT TO SUPPORT FDA'S PUBLIC HEALTH MISSION

- Sec. 601. Integrated strategy and management plan.
- Sec. 602. Independent assessment.

1 **TITLE I—ENSURING GREATER**  
2 **TRANSPARENCY AND AC-**  
3 **COUNTABILITY IN FDA REGU-**  
4 **LATORY DECISIONMAKING**

5 **SEC. 101. ADVANCING REGULATORY SCIENCE TO PROMOTE**  
6 **PUBLIC HEALTH AND INNOVATION.**

7 (a) IN GENERAL.—Not later than 1 year after the  
8 date of enactment of this Act, the Secretary of Health and  
9 Human Services (referred to in this section as the “Sec-  
10 retary”) shall develop a strategy and implementation plan  
11 for advancing regulatory science for medical products in  
12 order to promote the public health and advance innovation  
13 in regulatory decisionmaking.

14 (b) REQUIREMENTS.—The strategy and implementa-  
15 tion plan developed under subsection (a) shall be con-  
16 sistent with the user fee performance goals in the Pre-  
17 scription Drug User Fee Agreement commitment letter,  
18 the Generic Drug User Fee Agreement commitment letter,  
19 and the Biosimilar User Fee Agreement commitment let-  
20 ter transmitted by the Secretary to Congress on January  
21 13, 2012, and the Medical Device User Fee Agreement  
22 published in the Federal Register on March 20, 2012, and  
23 shall—

24 (1) identify a clear vision of the fundamental  
25 role of efficient, consistent, and predictable, science-

1 based decisions throughout regulatory decision-  
2 making of the Food and Drug Administration with  
3 respect to medical products;

4 (2) identify the regulatory science priorities of  
5 the Food and Drug Administration directly related  
6 to fulfilling the mission of the agency with respect  
7 to decisionmaking concerning medical products and  
8 allocation of resources towards these regulatory  
9 science priorities;

10 (3) identify regulatory and scientific gaps that  
11 impede the timely development and review of, and  
12 regulatory certainty with respect to, the approval, li-  
13 censure, or clearance of medical products, including  
14 with respect to companion products and new tech-  
15 nologies, and facilitating the timely introduction and  
16 adoption of new technologies and methodologies in a  
17 safe and effective manner;

18 (4) identify clear, measurable metrics by which  
19 progress on the priorities identified under paragraph  
20 (2) and gaps identified under paragraph (3) will be  
21 measured by the Food and Drug Administration, in-  
22 cluding metrics specific to the integration and adop-  
23 tion of advances in regulatory science described in  
24 paragraph (5) and improving medical product deci-

1 sionmaking, in a predictable and science-based man-  
2 ner; and

3 (5) set forth how the Food and Drug Adminis-  
4 tration will ensure that advances in regulatory  
5 science for medical products are adopted, as appro-  
6 priate, on an ongoing basis and in a manner inte-  
7 grated across centers, divisions, and branches of the  
8 Food and Drug Administration, including by senior  
9 managers and reviewers, including through the—

10 (A) development, updating, and consistent  
11 application of guidance documents that support  
12 medical product decisionmaking; and

13 (B) the adoption of the tools, methods, and  
14 processes under section 566 of the Federal  
15 Food, Drug, and Cosmetic Act (21 U.S.C.  
16 360bbb–5).

17 (c) ANNUAL PERFORMANCE REPORTS.—As part of  
18 the annual performance reports by the Food and Drug  
19 Administration to Congress, the Secretary shall annually  
20 report on the progress made with respect to—

21 (1) advancing the regulatory science priorities  
22 and resolving the gaps identified under paragraph  
23 (3) of subsection (b), including reporting on specific  
24 metrics identified under paragraph (4) of such sub-  
25 section;

1           (2) the integration and adoption of advances in  
2       regulatory science as set forth in paragraph (5) of  
3       such subsection; and

4           (3) the progress made in advancing the regu-  
5       latory science goals outlined in the Prescription  
6       Drug User Fee Agreement commitment letter, the  
7       Generic Drug User Fee Agreement commitment let-  
8       ter, and the Biosimilar User Fee Agreement commit-  
9       ment letter transmitted by the Secretary to Congress  
10      on January 13, 2012, and the Medical Device User  
11      Fee Agreement published in the Federal Register on  
12      March 20, 2012.

13      (d) INDEPENDENT ASSESSMENT.—Not later than  
14      January 1, 2016, the Comptroller General of the United  
15      States shall submit to Congress a report—

16           (1) detailing the progress made by the Food  
17       and Drug Administration in meeting the priorities  
18       and addressing the gaps identified in subsection (b),  
19       including any outstanding gaps; and

20           (2) containing recommendations, as appro-  
21       priate, on how regulatory science initiatives for med-  
22       ical products can be strengthened and improved to  
23       promote the public health and advance innovation in  
24       regulatory decisionmaking.

1 (e) MEDICAL PRODUCT.—In this section, the term  
 2 “medical product” means a drug, as defined in subsection  
 3 (g) of section 201 of the Federal Food, Drug, and Cos-  
 4 metic Act (21 U.S.C. 321), a device, as defined in sub-  
 5 section (h) of such section, or a biological product, as de-  
 6 fined in section 351(i) of the Public Health Service Act  
 7 (42 U.S.C. 262(i)).

8 **SEC. 102. REPORTING WITH RESPECT TO PRESCRIPTION**  
 9 **DRUGS.**

10 Section 736B of the Federal Food, Drug, and Cos-  
 11 metic Act (21 U.S.C. 379h–2) is amended—

12 (1) by amending subsection (a) to read as fol-  
 13 lows:

14 “(a) PERFORMANCE REPORT.—Beginning with fiscal  
 15 year 2013, not later than 120 days after the end of each  
 16 fiscal year for which fees are collected under this part,  
 17 the Secretary shall prepare and submit to the Committee  
 18 on Health Education, Labor, and Pensions of the Senate  
 19 and the Committee on Energy and Commerce of the  
 20 House of Representatives a report concerning—

21 “(1) the progress of the Food and Drug Admin-  
 22 istration in achieving the goals identified in the doc-  
 23 ument entitled, ‘PDUFA Reauthorization Perform-  
 24 ance Goals and Procedures Fiscal Years 2013  
 25 through 2017’, and included in the Prescription

1 Drug User Fee Agreement commitment letter trans-  
2 mitted by the Secretary to Congress on January 13,  
3 2012, during such fiscal year and the future plans  
4 of the Food and Drug Administration for meeting  
5 the goals; and

6 “(2) the progress of each review division and  
7 branch within the Center for Drug Evaluation and  
8 Research and the Center for Biologics Evaluation  
9 and Research in achieving such goals, and the plans  
10 of each such division and branch for meeting the  
11 goals, including—

12 “(A) the number of applications for ap-  
13 proval of a new drug under section 505(b) of  
14 this Act or a new biological product under sec-  
15 tion 351(a) of the Public Health Service Act  
16 filed per fiscal year by each review division and  
17 branch;

18 “(B) the number of such applications that  
19 did not meet the goals described in paragraph  
20 (1);

21 “(C) the percentage of such applications  
22 approved by each review division and branch;

23 “(D) the percentage of such applications  
24 found to be approvable by each review division  
25 and branch;



1           “(E) the percentage of such applications  
2           that were issued complete response letters by  
3           each review division and branch;

4           “(F) the percentage of such applications  
5           that were subject to a refuse-to-file action by  
6           each review division and branch;

7           “(G) the percentage of such applications  
8           withdrawn by each review division and branch;

9           “(H) the total number of review cycles per  
10          such approval and the average, mean, and me-  
11          dian number of review cycles per such applica-  
12          tion by each review division and branch;

13          “(I) the mean and median time to final de-  
14          cision, including approval, per such application  
15          by each review division and branch;

16          “(J) the average total time to decision by  
17          each review division and branch, including the  
18          number of days spent during the review by the  
19          Food and Drug Administration and days spent  
20          by the sponsor responding to a complete re-  
21          sponse letter;

22          “(K) the percentage of applications that  
23          are considered as fast track products under sec-  
24          tion 506 and through accelerated approval by  
25          each review division and branch; and

1                   “(L) the number of full-time equivalent po-  
 2                   sitions and overall budget assigned to each re-  
 3                   view division and branch.

4           “(b) INCLUSION.—The report under this section for  
 5 a fiscal year shall include information on all previous co-  
 6 horts for which the Secretary has not given a complete  
 7 response on all human drug applications and supplements  
 8 in the cohort.”; and

9           (2) in subsection (b), by inserting “, including  
 10 a qualitative and quantitative report with respect to  
 11 how user fees and appropriated funds are used for  
 12 the drug review process, including the percentage of  
 13 review time devoted to activities related to the review  
 14 of applications under subsections (b) and (j) of sec-  
 15 tion 505 and subsections (a) and (k) of section 351  
 16 of the Public Health Service Act” before the period  
 17 at the end.

18 **SEC. 103. REPORTING WITH RESPECT TO GENERIC DRUGS.**

19       Part 2 of subchapter C of chapter VII of the Federal  
 20 Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.)  
 21 is amended by adding at the end the following:

22 **“SEC. 736C. REPORTING WITH RESPECT TO GENERIC**  
 23 **DRUGS.**

24       “(a) IN GENERAL.—Beginning with fiscal year 2013,  
 25 not later than 120 days after the end of each fiscal year

1 for which fees are collected under this part, the Secretary  
2 shall prepare and submit to the Committee on Health  
3 Education, Labor, and Pensions of the Senate and the  
4 Committee on Energy and Commerce of the House of  
5 Representatives a report concerning—

6 “(1) the progress of the Food and Drug Admin-  
7 istration in achieving the goals identified in the Ge-  
8 neric Drug User Fee Act (GDUFA) proposal of the  
9 Food and Drug Administration, as set forth in the  
10 Generic Drug User Fee Agreement commitment let-  
11 ter dated January 13, 2012, during such fiscal year  
12 and the future plans of the Food and Drug Adminis-  
13 tration for meeting the goals; and

14 “(2) the progress of the Office of Generic  
15 Drugs within the Center for Drug Evaluation and  
16 Research and the Office of Regulatory Affairs in  
17 achieving such goals, and the plans of the Office of  
18 Generic Drugs, the Center for Drug Evaluation and  
19 the Office of Regulatory Affairs in meeting the  
20 goals, including—

21 “(A)(i) the progress in completing review  
22 of applications under section 505(j) of the Fed-  
23 eral Food, Drug, and Cosmetic Act, amend-  
24 ments to such applications, and prior approval  
25 supplements with respect to such applications

1 that have been pending for more than 10  
2 months, including applications under section  
3 505(j) that have been pending for more than 10  
4 months as of October 1, 2012, and prior ap-  
5 proval supplements to such applications that  
6 have been pending for more than 180 days as  
7 of October 1, 2012;

8 “(ii) the total number of applications  
9 under section 505(j), amendments to such ap-  
10 plications, and prior approval supplements with  
11 respect to such applications that have been  
12 pending for more than 10 months; and

13 “(iii) the average total time it takes to re-  
14 view and reach a final decision on—

15 “(I) applications under section 505(j);

16 “(II) major and minor amendments to  
17 applications under section 505(j); and

18 “(III) prior approval supplements  
19 with respect to applications under section  
20 505(j);

21 “(B) the number of such applications that  
22 did not meet the goals described in paragraph  
23 (1);

24 “(C) the total number of review cycles per  
25 approval of an application described in sub-

1 clause (I), (II), or (III) of subparagraph (A)(iii)  
2 and the average, mean, and median number of  
3 review cycles per such application by each re-  
4 view division and branch;

5 “(D) the number of meetings granted to  
6 industry and the number of meeting requests  
7 submitted by industry;

8 “(E) the mean and median time to final  
9 decision, including approval, per such applica-  
10 tion by the Office of Generic Drugs;

11 “(F) the median time frames and ranges  
12 for reporting decisions with respect to good  
13 manufacturing practices to the Office of Ge-  
14 neric Drugs following completion of inspections;

15 “(G) the median time frames for com-  
16 pleting requested foreign and domestic inspec-  
17 tions;

18 “(H) the total number of review cycles per  
19 such approval and the average, mean, and me-  
20 dian number of review cycles per such applica-  
21 tion;

22 “(I) the average total time to decision by  
23 the Office of Generic Drugs, including the num-  
24 ber of days spent during the review by the Food

1           and Drug Administration and days spent by the  
2           sponsor responding to a complete response; and  
3           “(J) the number of full-time equivalent po-  
4           sitions and overall budget assigned to the Office  
5           of Generic Drugs and each unit of the Food  
6           and Drug Administration.

7           “(b) INCLUSION.—The report under this section for  
8   a fiscal year shall include information on all previous co-  
9   horts for which the Secretary has not given a complete  
10  response on all human drug applications and supplements  
11  in the cohort.

12          “(c) FISCAL REPORT.—Beginning not later than fis-  
13  cal year 2013, not later than 120 days after the end of  
14  each fiscal year, the Secretary shall prepare and submit  
15  to the Committee on Health, Education, Labor, and Pen-  
16  sions of the Senate and the Committee on Energy and  
17  Commerce of the House of Representatives a report on  
18  the implementation of the authority for any user fees with  
19  respect to generic drugs during such fiscal year, and the  
20  use, by the Food and Drug Administration, of any such  
21  fees collected for such fiscal year, including a qualitative  
22  and quantitative report with respect to how user fees and  
23  appropriated funds are used for the drug review process,  
24  including the percentage of review time devoted to direct  
25  review of applications under section (j) of section 505.”.

1 **SEC. 104. REPORTING WITH RESPECT TO BIOSIMILARS.**

2 Part 2 of subchapter C of chapter VII of the Federal  
3 Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.),  
4 as amended by section 103, is further amended by adding  
5 at the end the following:

6 **“SEC. 736D. REPORTING WITH RESPECT TO BIOSIMILARS.**

7 “(a) PERFORMANCE REPORT.—Beginning with fiscal  
8 year 2013, not later than 120 days after the end of each  
9 fiscal year for which fees are collected under this part,  
10 the Secretary shall prepare and submit to the Committee  
11 on Energy and Commerce of the House of Representatives  
12 and the Committee on Health, Education, Labor, and  
13 Pensions of the Senate a report concerning—

14 “(1) the progress of the Food and Drug Admin-  
15 istration in achieving the goals identified in the  
16 Biosimilars User Fee Act (BSUFA) proposal of the  
17 Food and Drug Administration, as set forth in the  
18 Biosimilar User Fee Agreement commitment letter  
19 dated January 13, 2012, during such fiscal year and  
20 the future plans of the Food and Drug Administra-  
21 tion for meeting the goals; and

22 “(2) the progress of each review division and  
23 branch within the Center for Drug Evaluation and  
24 Research and the Center for Biologics Evaluation  
25 and Research in achieving the goals, and the plans

1 of each such division and branch for meeting the  
2 goals, including—

3 “(A) the number of applications for ap-  
4 proval under section 351(k) of the Public  
5 Health Service Act filed per fiscal year by each  
6 review division and branch;

7 “(B) the number of such applications that  
8 did not meet the goals described in paragraph  
9 (1) and the total time elapsed since such appli-  
10 cations were submitted, including the time such  
11 application was with the Food and Drug Ad-  
12 ministration and the time such application was  
13 with the sponsor;

14 “(C) the percentage of such applications  
15 approved by each review division and branch;

16 “(D) the percentage of such applications  
17 that were issued complete response letters by  
18 each review division and branch;

19 “(E) the percentage of such applications  
20 that were subject to a refuse-to-file action by  
21 each review division and branch;

22 “(F) the percentage of such applications  
23 withdrawn by the sponsor by each review divi-  
24 sion and branch;



1           “(G) the total number of review cycles per  
2           each approval and the average, mean, and me-  
3           dian review cycles per such application (or for  
4           all approvals) by each review division and  
5           branch;

6           “(H) the mean and median time to final  
7           decision, including approval, per such applica-  
8           tion by each review division and branch; and

9           “(I) the number of full-time equivalent po-  
10          sitions and overall budget assigned to each re-  
11          view division and branch.

12       “(b) INCLUSION.—The report under this subsection  
13       for a fiscal year shall include information on all previous  
14       cohorts for which the Secretary has not given a complete  
15       response on all applications under section 351(k) of the  
16       Public Health Service Act in the cohort.

17       “(c) FISCAL REPORT.—Beginning not later than fis-  
18       cal year 2013, not later than 120 days after the end of  
19       each fiscal year, the Secretary shall prepare and submit  
20       to the Committee on Health, Education, Labor, and Pen-  
21       sions of the Senate and the Committee on Energy and  
22       Commerce of the House a report on the implementation  
23       of the authority for any user fees with respect to biological  
24       products approved under section 351(k) of the Public  
25       Health Service Act during such fiscal year, and the use,

1 by the Food and Drug Administration, of any such fees  
 2 collected for such fiscal year, including a qualitative and  
 3 quantitative report with respect to how user fees and ap-  
 4 propriated funds are used for the drug review process, in-  
 5 cluding the percentage of review time devoted to direct re-  
 6 view of applications under subsections (a) and (k) of sec-  
 7 tion 351 of the Public Health Service Act.”.

8 **SEC. 105. DOCUMENTATION OF REGULATORY DECISIONS.**

9 Chapter V of the Federal Food, Drug, and Cosmetic  
 10 Act (21 U.S.C. 351 et seq.) is amended by adding at the  
 11 end the following:

12 **“SEC. 524A. AGENCY DOCUMENTATION OF SIGNIFICANT DE-**  
 13 **CISIONS REGARDING DRUGS AND DEVICES.**

14 “(a) DOCUMENTATION OF RATIONALE FOR SIGNIFI-  
 15 CANT DECISIONS.—The Secretary shall document the sci-  
 16 entific and regulatory rationale for any significant deci-  
 17 sion—

18 “(1) of the Center for Drug Evaluation and Re-  
 19 search regarding an application under subsection (b)  
 20 or (j) of section 505;

21 “(2) of the Center for Biologics Evaluation and  
 22 Research regarding an application under subsection  
 23 (a) or (k) of section 351 of the Public Health Serv-  
 24 ice Act; and

1           “(3) of the Center for Devices and Radiological  
2       Health regarding submission or review of a report  
3       under section 510(k), an application under section  
4       515, or an application for an exemption under sec-  
5       tion 520(g).

6       “(b) PROVISION OF DOCUMENTATION.—Upon re-  
7       quest, the Secretary shall furnish such documentation to  
8       the person who is seeking to submit, or who has sub-  
9       mitted, such report or application.”.

10   **SEC. 106. REVIEW OF REGULATIONS AND GUIDANCE.**

11       Not later than 1 year after the date of enactment  
12       of this Act, the Secretary of Health and Human Services  
13       shall review all regulations and guidance of the Food and  
14       Drug Administration with respect to human medical prod-  
15       ucts (as defined in section 101) to ensure consistency  
16       with—

17       (a) the requirements of the Federal, Food, Drug, and  
18       Cosmetic Act (21 U.S.C. 301 et seq.); and

19       (b) the regulatory principles of the benefits of such  
20       regulations and guidance justifying the costs and adoption  
21       of the least burdensome approaches to such regulation and  
22       guidance as outlined in Executive Order 13563, dated  
23       January 18, 2011.

1 **SEC. 107. LEVERAGING INFORMATION TECHNOLOGY TO**  
2 **FULFILL FDA'S PUBLIC HEALTH MISSION.**

3 (a) HHS REPORT.—Not later than 1 year after the  
4 date of enactment of this Act, the Secretary of Health and  
5 Human Services shall—

6 (1) report to Congress on—

7 (A) the milestones and a completion date  
8 for developing and implementing a comprehen-  
9 sive information technology strategic plan to  
10 align the information technology systems mod-  
11 ernization projects with the strategic goals of  
12 the Food and Drug Administration, including  
13 results-oriented goals, strategies, milestones,  
14 performance measures;

15 (B) efforts to finalize and approve a com-  
16 prehensive inventory of the information tech-  
17 nology systems of the Food and Drug Adminis-  
18 tration that includes information describing  
19 each system, such as costs, system function or  
20 purpose, and status information, and incor-  
21 porate use of the system portfolio into the in-  
22 formation investment management process of  
23 the Food and Drug Administration;

24 (C) the ways in which the Food and Drug  
25 Administration uses the plan described in sub-  
26 paragraph (A) to guide and coordinate the

1 modernization projects and activities of the  
2 Food and Drug Administration, including the  
3 interdependencies among projects and activities;  
4 and

5 (D) the extent to which the Food and  
6 Drug Administration has fulfilled or is imple-  
7 menting recommendations of the Government  
8 Accountability Office with respect to the Food  
9 and Drug Administration and information tech-  
10 nology; and

11 (2) develop—

12 (A) a documented enterprise architecture  
13 program management plan that includes the  
14 tasks, activities, and timeframes associated with  
15 developing and using the architecture and ad-  
16 dresses how the enterprise architecture program  
17 management will be performed in coordination  
18 with other management disciplines, such as or-  
19 ganizational strategic planning, capital planning  
20 and investment control, and performance man-  
21 agement; and

22 (B) a skills inventory, needs assessment,  
23 gap analysis, and initiatives to address skills  
24 gaps as part of a strategic approach to informa-  
25 tion technology human capital planning.

1 (b) GAO REPORT.—Not later than January 1, 2016,  
2 the Comptroller General of the United States shall issue  
3 a report regarding the strategic plan described in sub-  
4 section (a) and related actions carried out by the Food  
5 and Drug Administration. Such report shall assess the  
6 progress the Food and Drug Administration has made  
7 on—

8 (1) the development and implementation of a  
9 comprehensive information technology strategic plan,  
10 including the results-oriented goals, strategies, mile-  
11 stones, and performance measures identified in sub-  
12 paragraph (a);

13 (2) the effectiveness of the comprehensive infor-  
14 mation technology strategic plan in subparagraph  
15 (a), including the results-oriented goals and perform-  
16 ance measures; and

17 (3) the extent to which the Food and Drug Ad-  
18 ministration has fulfilled recommendations of the  
19 Government Accountability Office with respect to  
20 such agency and information technology.

## 21 **TITLE II—RECALIBRATING RISK-** 22 **BENEFIT CONSIDERATIONS**

### 23 **SEC. 201. DEVICES.**

24 Section 513(a) of the Federal Food, Drug, and Cos-  
25 metic Act (21 U.S.C. 360(a)) is amended—

1 (1) in paragraph (2)—

2 (A) by redesignating subparagraphs (A)  
3 through (C) as clauses (i) through (iii), respec-  
4 tively,

5 (B) by striking “(2) For” and inserting  
6 “(2)(A) For”; and

7 (C) by adding at the end the following:

8 “(B) The Secretary shall assess the safety and  
9 effectiveness of a device as required under subpara-  
10 graph (A) from the perspective of a reasonable pa-  
11 tient in the intended use population who would as-  
12 sign the most value to the effect the device purports  
13 to have or is represented to have under the condi-  
14 tions of use prescribed, recommended, or suggested  
15 in the labeling or proposed labeling, and who would  
16 be willing to accept the probable risks that may be  
17 associated with the use of the device as prescribed,  
18 recommended, or suggested in the labeling or pro-  
19 posed labeling.”;

20 (2) by redesignating paragraph (3) as para-  
21 graph (4); and

22 (3) by inserting after paragraph (2) the fol-  
23 lowing:

24 “(3)(A) The safety of a device is, for purposes  
25 of this section and sections 514 and 515, to be de-

1       terminated in accordance with regulations promul-  
2       gated by the Secretary, on the basis of information  
3       contained in the application and valid scientific evi-  
4       dence derived from well-controlled investigations.  
5       The Secretary shall not find a lack of reasonable as-  
6       surance of safety unless information contained in the  
7       application or valid scientific evidence demonstrates  
8       that there is a reasonable probability of a risk of in-  
9       jury or illness from the proposed use of the device  
10      that is not outweighed by the probable benefit to  
11      health from the device.

12           “(B) The Secretary may determine there is not  
13      reasonable assurance of safety with respect to a de-  
14      vice only after identifying in writing—

15                   “(i) the probable risk of injury or illness;

16                   “(ii) the scientific evidence that reasonably  
17                   supports the Secretary’s determination; and

18                   “(iii) the type of data or information, con-  
19                   sistent with the least burdensome provisions of  
20                   this Act, that would demonstrate a benefit that  
21                   would exceed the probable risk.”.

22   **SEC. 202. DRUGS.**

23       Section 505(d) of the Federal Food, Drug, and Cos-  
24      metic Act (21 U.S.C. 355(d)) is amended by adding at  
25      the end the following:



1 “In assessing the safety and effectiveness of a drug under  
 2 this subsection, the Secretary shall implement a struc-  
 3 tured benefit-risk assessment framework in the new drug  
 4 approval process to facilitate the balanced consideration  
 5 of benefits and risks, a consistent and systematic approach  
 6 to the discussion and regulatory decisionmaking, and the  
 7 communication of the benefits and risks of new drugs.”.

## 8 **TITLE III—REDUCING UNNECES-** 9 **SARY DELAYS AND REGU-** 10 **LATORY BURDENS**

### 11 **SEC. 301. OPTIMIZING GLOBAL CLINICAL TRIALS.**

12 Subchapter E of chapter V of the Federal Food,  
 13 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is  
 14 amended by adding at the end the following:

#### 15 **“SEC. 568. OPTIMIZING GLOBAL CLINICAL TRIALS.**

16 “For purposes of eliminating costly and scientifically  
 17 unnecessary clinical trials, enhancing the efficiency of  
 18 medical products development, and facilitating the Food  
 19 and Drug Administration and the acceptance of foreign  
 20 clinical data of other health authorities, the Food and  
 21 Drug Administration shall—

22 “(1) work with other regulatory authorities of  
 23 similar standing, medical research companies, and  
 24 international organizations to foster and encourage

1 uniform, scientifically-driven clinical trial standards  
 2 around the world; and

3 “(2) enhance the commitment to provide the  
 4 least burdensome, consistent parallel scientific advice  
 5 to manufacturers seeking simultaneous global devel-  
 6 opment of new medical products in order to mini-  
 7 mize the need for conduct and duplication of clinical  
 8 studies, preclinical studies, or non-clinical studies.”.

9 **SEC. 302. ADVANCING AMERICAN PATIENTS’ TIMELY AC-**  
 10 **CESS TO INNOVATIVE DEVICES.**

11 Section 520(g) of the Federal Food, Drug, and Cos-  
 12 metic Act (21 U.S.C. 360j(g)) is amended by adding at  
 13 the end the following:

14 “(8) In the case of a person intending to inves-  
 15 tigate the safety or effectiveness of a class II or a  
 16 class III device that—

17 “(A) has a valid marketing authorization  
 18 by the appropriate authority in Australia, Can-  
 19 ada, Israel, Japan, New Zealand, Switzerland,  
 20 or South Africa or in the European Union or  
 21 a country in the European Economic Area (the  
 22 countries in the European Union and the Euro-  
 23 pean Free Trade Association), or such other  
 24 authority recognized by the Secretary; and

1           “(B) has a history of use pursuant to its  
2           marketing authorization with no device-related  
3           serious unanticipated adverse event reports,  
4           the Secretary shall permit an exemption for clinical  
5           testing of such device for the purpose of developing  
6           data to obtain clearance or approval for the commer-  
7           cial distribution of such device.”.

8   **SEC. 303. ENSURING LEGAL SUFFICIENCY AND CONSIST-**  
9                           **ENCY OF FDA ENFORCEMENT POLICIES.**

10          Subchapter E of chapter V of the Federal Food,  
11   Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.), as  
12   amended by section 301, is further amended by adding  
13   at the end the following:

14   **“SEC. 569. WARNING LETTERS.**

15          “(a) IN GENERAL.—Before a warning letter with re-  
16   spect to a drug or device is issued, the Office of the Chief  
17   Counsel shall review such warning letter to ensure that  
18   such warning letter is legally sufficient and consistent with  
19   all policies of the Food and Drug Administration.

20          “(b) WARNING LETTER.—For purposes of this sec-  
21   tion, the term ‘warning letter’ shall include all notices of  
22   alleged violations, including untitled letters.”.

1 **TITLE IV—STRENGTHENING AD-**  
2 **VISORY COMMITTEES FOR PA-**  
3 **TIENTS**

4 **SEC. 401. STRENGTHENING ADVISORY COMMITTEES FOR**  
5 **PATIENTS.**

6 (a) FINDING.—Congress finds that—

7 (1) as science becomes more specialized, it be-  
8 comes more difficult for general scientists to keep up  
9 with the scientific advances in the many areas that  
10 the Food and Drug Administration regulates;

11 (2) it is necessary for the Food and Drug Ad-  
12 ministration to be able to draw upon essential med-  
13 ical and scientific expertise across specialized areas  
14 in order to fulfill its public health mission;

15 (3) the programs with respect to advisory com-  
16 mittees under the Food and Drug Administration  
17 should be strengthened and improved to ensure that  
18 the Food and Drug Administration is able to be ad-  
19 vised by the most qualified medical and scientific  
20 subject experts; and

21 (4) an appropriate balance should be restored  
22 with respect to conflict of interest considerations for  
23 advisory committees and experts advising the Food  
24 and Drug Administration to ensure that the Food

1 and Drug Administration is able to draw upon the  
 2 most qualified medical and scientific experts.

3 (b) ADVISORY COMMITTEES AND SPECIAL GOVERN-  
 4 MENT EMPLOYEES.—Subchapter A of chapter VII of the  
 5 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371  
 6 et seq.) is amended by adding at the end the following:

7 **“SEC. 714. STRENGTHENING ADVISORY COMMITTEES.**

8 “(a) INCREASING NUMBERS OF MEDICAL AND SCI-  
 9 ENTIFIC SPECIALISTS PROVIDING EXPERTISE AND AN-  
 10 NUAL REPORT.—

11 “(1) SPECIAL GOVERNMENT EMPLOYEES.—In  
 12 this section, the term ‘special Government employee’  
 13 has the meaning given the term in section 202 of  
 14 title 18, United States Code.

15 “(2) INCREASING NUMBERS.—The Secretary,  
 16 acting through the Commissioner of Food and  
 17 Drugs, shall collaborate with stakeholders, including  
 18 consumer groups, patient groups, academia, and in-  
 19 dustry representatives, to increase the number of  
 20 special Government employees across medical and  
 21 scientific specialties in areas where the Secretary  
 22 lacks specific scientific, medical, or technical exper-  
 23 tise necessary for the performance of its regulatory  
 24 responsibilities.

1           “(3) ANNUAL REPORTS.—The Secretary, acting  
 2           through the Commissioner of Food and Drugs, shall  
 3           submit an annual report, as part of the annual user  
 4           fee agreement performance report, on the manage-  
 5           ment of the pool of special Government employees of  
 6           the Food and Drug Administration by citing—

7                   “(A) the total number of such employees;

8                   “(B) the employees’ specific areas of ex-  
 9           pertise;

10                  “(C) the turnover by resignation of such  
 11           employees;

12                  “(D) new special Government employee ap-  
 13           pointments;

14                  “(E) the frequency of participation by spe-  
 15           cial Government employees in decisions by the  
 16           Food and Drug Administration or advice pro-  
 17           vided to the Food and Drug Administration;  
 18           and

19                  “(F) the total number of applicants not se-  
 20           lected to serve as special government employees.

21           “(b) TEMPLATE FOR ADVISORY COMMITTEE BY-  
 22   LAWS.—The Secretary, acting through the Commissioner  
 23   of Food and Drugs, shall—

1 “(1) publish a standardized template for the by-  
 2 laws of advisory committees established under this  
 3 Act; and

4 “(2) require each of such advisory committees  
 5 to compile and publish online an annual report con-  
 6 taining, at a minimum—

7 “(A) a list of the members of the advisory  
 8 committee, the business address of each mem-  
 9 ber, and the dates of each member’s term;

10 “(B) a list of the Chair and any other des-  
 11 ignated leaders of the Advisory Committee;

12 “(C) a list of any vacancies on the advisory  
 13 committee and the length of any vacancy;

14 “(D) the advisory committee’s functions,  
 15 expenditures, the dates and places of meetings,  
 16 and the attendance of members present at such  
 17 meetings; and

18 “(E) a summary of the advisory commit-  
 19 tee’s activities and recommendations made dur-  
 20 ing the fiscal year.

21 “(c) TEMPLATE FOR PUBLICATION OF CVs.—

22 “(1) IN GENERAL.—The Secretary, acting  
 23 through the Commissioner of Food and Drugs, shall  
 24 collaborate with stakeholders, including consumer  
 25 groups, patient groups, academia, and industry rep-

1        representatives, to publish a standardized template as  
2        guidance for special Government employees of the  
3        Food and Drug Administration and members of ad-  
4        visory committees established under this Act to use  
5        in publicizing their curriculum vitae.

6                “(2) CONTENT OF TEMPLATE.—The standard-  
7        ized template described in paragraph (1) shall be  
8        consistent with the following:

9                “(A) Peer-reviewed research shall be sepa-  
10       rated from non-peer-reviewed research.

11               “(B) The template shall include a separate  
12       list of research that has been submitted for re-  
13       view but not yet published.

14               “(C) The template shall include a separate  
15       list of non-research publications.

16               “(D) The template shall include general in-  
17       formation about the topic and date in cases  
18       where the research or grant subject matter has  
19       been redacted.

20               “(E) All items shall be listed in chrono-  
21       logical order beginning with the most recent.

22               “(d) AFFIDAVITS.—The Secretary may require mem-  
23       bers of advisory committees established under this Act to  
24       sign an affidavit stating that the member has read the  
25       majority of the briefing materials pertinent to the decision



1 or advice and agrees to the code of conduct to serve as  
2 a special government employee.

3 “(e) REPORT.—

4 “(1) IN GENERAL.—Not later than January 1,  
5 2017, the Secretary, acting through the Commis-  
6 sioner of Food and Drugs, shall report to Congress  
7 on the issue of temporary members serving on advi-  
8 sory committees established under this Act.

9 “(2) CONTENT OF REPORT.—The report de-  
10 scribed in paragraph (1) shall include the following  
11 information:

12 “(A) How many temporary members have  
13 served on advisory committees established  
14 under this Act and how many temporary mem-  
15 bers served on each advisory committee.

16 “(B) What percentage of such temporary  
17 members were called upon to offer subject mat-  
18 ter expertise in voting or to reach a quorum.

19 “(C) Whether temporary members offer  
20 expertise on an issue being decided.

21 “(D) Whether temporary members being  
22 called upon merely to reach a quorum.

23 “(E) How temporary members are se-  
24 lected.”.

**TITLE V—MEDICAL DEVICE  
REGULATORY IMPROVEMENTS  
Subtitle A—Premarket  
Predictability**

**SEC. 501. TRACKING AND REVIEW OF APPLICATIONS FOR  
INVESTIGATIONAL DEVICE EXEMPTIONS.**

Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

“(8)(A) Upon the submission of an application for an exemption for a device under this subsection, the submission of a request to classify a device under section 513, or the submission of a report for a device under section 510(k), whichever occurs first, the Secretary shall assign a tracking number to the device.

“(B) The Secretary shall use such tracking number to record the following interactions between the Secretary and applicant with respect to the device:

“(i) Submission or approval of an application for an exemption under this subsection.

“(ii) Submission of a request to classify the device under section 513.

“(iii) Submission or clearance of a report under section 510(k).

1           “(iv) Any meeting or meeting request, including  
2           in anticipation of the submission of such an applica-  
3           tion or report.

4           “(v) Submission or approval of an application  
5           under section 515(c).

6           “(vi) Any formal or informal request by the  
7           Secretary for additional information.

8           “(vii) Any deficiency letter.

9           “(viii) Any response by the applicant to a re-  
10          quest described in clause (v) or a deficiency letter.

11          “(ix) Any written submission by the applicant  
12          to the Food and Drug Administration.

13          “(x) Any other matter, as determined appro-  
14          priate by the Secretary.

15          “(9) Upon the submission of an application for an  
16          exemption under this subsection for a device, the Sec-  
17          retary shall assign, to review the application, a reviewer  
18          with prior review experience with that type of device or  
19          technology or other relevant expertise.”.

20       **SEC. 502. INVESTIGATIONAL DEVICE EXEMPTIONS.**

21          Section 520(g) of the Federal Food, Drug, and Cos-  
22          metic Act (21 U.S.C. 360j(g)) is amended—

23               (1) in paragraph (2)(B)(ii), by inserting “safety  
24          and effectiveness” after “Secretary of”; and

1           (2) in paragraph (4), by adding at the end the  
2       following:

3           “(C) Consistent with paragraph (1), the  
4       Secretary shall not disapprove an application  
5       under this subsection because the Secretary de-  
6       termines—

7           “(i) that the investigation may not  
8       support a substantial equivalence or de  
9       novo classification determination or ap-  
10      proval of the device;

11          “(ii) that the investigation may not  
12      meet a requirement, including a data re-  
13      quirement, relating to the approval or  
14      clearance of a device; or

15          “(iii) that an additional or different  
16      investigation may be necessary to support  
17      clearance or approval of the device.”.

18 **SEC. 503. DEVICE SUBMISSION ACCEPTANCE CRITERIA.**

19       (a) IN GENERAL.—To ensure more efficient and  
20      timely evaluation of devices, the Secretary of Health and  
21      Human Services (referred to in this section as the “Sec-  
22      retary”) shall revise the device submission acceptance cri-  
23      teria utilized by the Secretary under chapter V of the Fed-  
24      eral Food, Drug, and Cosmetic Act (21 U.S.C. 351 et

1 seq.) as in effect on the date of enactment of this Act  
2 and implement such revised criteria.

3 (b) DESCRIPTION; CONTENT.—

4 (1) DESCRIPTION.—The revised acceptance cri-  
5 teria described under subsection (a) shall be objec-  
6 tive and consistent with the Federal Food, Drug,  
7 and Cosmetic Act and regulations issued under such  
8 Act (as in effect on the date of enactment of this  
9 Act).

10 (2) CONTENT.—Under such revised criteria, the  
11 Secretary's decision to refuse to accept or file a de-  
12 vice submission shall be consistent with the require-  
13 ments for such submission as set forth in the Fed-  
14 eral Food, Drug, and Cosmetic Act and the regula-  
15 tions issued under such Act (as in effect on the date  
16 of enactment of this Act), and shall not be based on  
17 criteria inconsistent with the Federal Food, Drug,  
18 and Cosmetic Act or such regulations.

19 (c) REPORT.—Not later than 2 years after the date  
20 of enactment of this Act, the Comptroller General of the  
21 United States shall issue a report regarding the device  
22 submission acceptance criteria. The Comptroller General  
23 shall, in consultation with persons accredited under sec-  
24 tion 523 of the Federal Food, Drug, and Cosmetic Act  
25 (21 U.S.C. 360m), assess and report on the clarity of the

1 revised device submission acceptance criteria under this  
2 section, and the effectiveness of the outcome measures  
3 adopted by the Center for Device and Radiological Health  
4 to ensure the consistent, appropriate, and predictable ap-  
5 plication of such device submission acceptance criteria  
6 consistent with the Federal Food, Drug, and Cosmetic Act  
7 and regulations issued under such Act (as in effect on the  
8 date of enactment of this Act).

9 **SEC. 504. TRANSPARENCY IN CLEARANCE PROCESS.**

10 (a) PUBLICATION OF DETAILED DECISION SUM-  
11 MARIES.—Section 520(h) (21 U.S.C. 360j(h)) is amended  
12 by adding at the end the following:

13 “(5) Subject to subsection (c) and section 301(j), the  
14 Secretary shall regularly publish detailed decision sum-  
15 maries for each clearance of a device under section  
16 510(k).”.

17 (b) APPLICATION.—The requirement of section  
18 520(h)(5) of the Federal Food, Drug, and Cosmetic Act,  
19 as added by subsection (a), applies only with respect to  
20 clearance of a device occurring after the date of the enact-  
21 ment of this Act.

1 **SEC. 505. RESTORING REGULATORY CERTAINTY WITH RE-**  
2 **SPECT TO 510(k) REPORTS REQUIRED FOR**  
3 **CERTAIN MODIFICATIONS.**

4 (a) IN GENERAL.—Section 510(n) of the Federal  
5 Food, Drug, and Cosmetic Act (21 U.S.C. 360(n)) is  
6 amended—

7 (1) by striking “(n) The Secretary” and insert-  
8 ing “(n)(1) The Secretary”; and

9 (2) by adding at the end the following:

10 “(2) A report under subsection (k) is not required  
11 for a modification to a device that has been classified into  
12 class I or II under subsection (f)(1) or (i) of section 513  
13 if—

14 “(A) the change is—

15 “(i) validated by same method applied to  
16 the classified device undergoing modification, or  
17 a current validation method that is equivalent  
18 to the validation method applied to the device  
19 undergoing modification;

20 “(ii) the validation identified under clause  
21 (i) includes all changes to the last version of the  
22 device that the Secretary found substantially  
23 equivalent to a predicate device, within the  
24 meaning of subsections (f)(1) and (i) of section  
25 513; and

1           “(iii) the validation of the modified device  
2           reveals that the safety and effectiveness results  
3           are consistent with the validation results of the  
4           unmodified device;

5           “(B) the device’s intended use remains the  
6           same; and

7           “(C) the information identified under subpara-  
8           graphs (A) and (B) is documented and maintained  
9           as part of the design file subject to inspection by the  
10          Secretary under section 704(a) for a period of time  
11          equal to the design life of the device, or 2 years from  
12          the date of the first commercial distribution of the  
13          modified device, whichever occurs later.”.

14          (b) REGULATIONS.—Not later than 1 year after the  
15          date of the enactment of this Act, the Secretary shall pro-  
16          mulgate a final regulation to implement section 510(n)(2)  
17          of the Federal Food, Drug, and Cosmetic Act, as added  
18          by subsection (a), including to define the phrase “signifi-  
19          cantly affect the safety or effectiveness of the device” con-  
20          sistent with the substantive criteria of clauses (i) through  
21          (iii) of section 510(n)(2)(A).

22          (c) ANNUAL REPORT.—The Secretary shall annually  
23          submit to the Committee on Health, Education, Labor,  
24          and Pensions of the Senate and the Committee on Energy  
25          and Commerce of the House of Representatives, a report



1 that specifies, with respect to the preceding 2-year pe-  
 2 riod—

3 (1) the number of reports submitted under sub-  
 4 section 510(k) for a modification or change to a de-  
 5 vice that was cleared under such subsection prior to  
 6 such modification or change; and

7 (2) the number of such reports submitted in re-  
 8 sponse to—

9 (A) a request from the Secretary,

10 (B) an observation made by the Secretary  
 11 during an inspection of an applicant’s facility;  
 12 or

13 (C) any other enforcement action initiated  
 14 by the Secretary.

15 **SEC. 506. MEETING THE DEVICE NEEDS OF INDIVIDUAL PA-**  
 16 **TIENTS.**

17 Chapter V of the Federal Food, Drug, and Cosmetic  
 18 Act (21 U.S.C. 351 et seq.) is amended by inserting after  
 19 section 515A the following:

20 **“SEC. 515B. MEETING THE DEVICE NEEDS OF INDIVIDUAL**  
 21 **PATIENTS.**

22 “(a) CUSTOM DEVICES.—Sections 514 and 515 shall  
 23 not apply to any device modified to meet the individual  
 24 needs of a specific patient if such device—

1           “(1) in order to comply with the order of an in-  
2       dividual physician or dentist (or any other specially  
3       qualified person designated under regulations pro-  
4       mulgated by the Secretary after an opportunity for  
5       an oral hearing), necessarily deviates from an other-  
6       wise applicable performance standard or requirement  
7       prescribed by or under section 515;

8           “(2) is not generally available in the United  
9       States in finished form and no other devices are do-  
10      mestically available to treat the unique pathology or  
11      physiological condition of the specific patient;

12          “(3) is intended to meet the special needs of  
13      such physician or dentist (or other specially qualified  
14      person so designated)—

15           “(A) in the course of the professional prac-  
16      tice of such physician or dentist (or other spe-  
17      cially qualified person so designated);

18           “(B) the need for which has been docu-  
19      mented in the patient’s medical record by such  
20      physician or dentist (or other specially qualified  
21      person so designated); and

22           “(C) is for use by the individual patient  
23      described in subparagraph (B); and

24          “(4) is—

1                   “(A) assembled from components or manu-  
2                   factured on a case-by-case basis;

3                   “(B) premanufactured and finished on a  
4                   case-by-case basis; or

5                   “(C) a modification to an existing, legally  
6                   marketed device.

7           “(b) LIMITATIONS.—Subsection (a) shall apply to a  
8           device only if—

9                   “(1) such device includes particular features to  
10                  accommodate a specific patient’s unique anatomical,  
11                  physiological, or clinical needs;

12                  “(2) such device is for the purpose of treating  
13                  sufficiently rare patient conditions, such that con-  
14                  ducting clinical investigations would be impractical;  
15                  and

16                  “(3) production of such device is limited to no  
17                  more than 10 units per year of a particular device  
18                  meeting a specific patient need or exhibiting a spe-  
19                  cific feature.”.

1 **Subtitle B—FDA Renewing Effi-**  
2 **ciency From Outside Reviewer**  
3 **Management**

4 **SEC. 511. PERSONS ACCREDITED TO REVIEW REPORTS**  
5 **UNDER SECTION 510(k) AND MAKE REC-**  
6 **OMMENDATIONS FOR INITIAL CLASSIFICA-**  
7 **TION.**

8 (a) TIME PERIOD FOR REVIEW OF RECOMMENDA-  
9 TIONS OF ACCREDITED PERSONS.—Section 523(a) (21  
10 U.S.C. 360m(a)) is amended—

11 (1) in paragraph (1), by striking “reviewing re-  
12 ports” and inserting “reviewing, and making rec-  
13 ommendations to the Secretary regarding, reports”;  
14 and

15 (2) in paragraph (2), by amending subpara-  
16 graph (B) to read as follows:

17 “(B) TIME PERIOD FOR REVIEW.—Not  
18 later than 30 days after the date on which the  
19 Secretary is notified under subparagraph (A) by  
20 an accredited person with respect to a rec-  
21 ommendation regarding a report submitted  
22 under section 510(k) or an initial classification  
23 of a device, the Secretary shall make a deter-  
24 mination with respect to the recommendation.”.

1       (b) ACCESS TO DEVICE INFORMATION.—Section  
 2 523(a)(2) (21 U.S.C. 360m(a)(2)), as amended by sub-  
 3 section (a)(2), is amended by adding at the end the fol-  
 4 lowing:

5               “(D) ACCESS TO DEVICE INFORMATION.—

6               “(i) IN GENERAL.—Subject to section  
 7 301(j), for the purpose of providing accred-  
 8 ited persons with additional information to  
 9 review reports submitted under section  
 10 510(k) and make recommendations regard-  
 11 ing the initial classification of devices, the  
 12 Secretary shall regularly publish—

13               “(I) detailed decision summaries  
 14 for each substantial equivalence deter-  
 15 mination under section 513(f)(1) and  
 16 each initial classification under section  
 17 513(f)(2); and

18               “(II) total product life cycles in-  
 19 formation for each device classified  
 20 under section 513(f).

21               “(ii) REQUIREMENT.—Any informa-  
 22 tion published under this subparagraph  
 23 shall be consistent with the requirements  
 24 of part 20 of title 21, Code of Federal

1 Regulations (or any successor regula-  
2 tions).”.

3 (c) ACCREDITATION.—Section 523(b) (21 U.S.C.  
4 360m(b)) is amended—

5 (1) in paragraph (2)—

6 (A) in the heading of subparagraph (C), by  
7 inserting “AND TRAINING” after “AUDITING”;

8 (B) in subparagraph (C)—

9 (i) in clause (i), by striking “and” at  
10 the end;

11 (ii) by redesignating clause (ii) as  
12 clause (iii); and

13 (iii) by inserting after clause (i) the  
14 following:

15 “(ii) provide for the initial training  
16 and periodic updating of training of such  
17 person; and”; and

18 (C) by adding at the end the following:

19 “(E) PERIODIC REACCREDITATION.—

20 “(i) PERIOD.—Subject to suspension  
21 or withdrawal under subparagraph (B),  
22 any accreditation under this section shall  
23 be valid for a period of 3 years after its  
24 issuance.

1                   “(ii) RESPONSE TO REACCREDITATION  
 2                   REQUEST.—Upon the submission of a re-  
 3                   quest by an accredited person for re-  
 4                   accreditation under this section, the Sec-  
 5                   retary shall approve or deny such request  
 6                   not later than 60 days after receipt of the  
 7                   request.

8                   “(iii) CRITERIA.—Not later than 120  
 9                   days after the date of the enactment of  
 10                  this subparagraph, the Secretary shall es-  
 11                  tablish and publish in the Federal Register  
 12                  criteria to reaccredit or deny reaccredita-  
 13                  tion to persons under this section. The re-  
 14                  accreditation of persons under this section  
 15                  shall specify the particular activities under  
 16                  subsection (a) for which such persons are  
 17                  reaccredited.”;

18                  (2) in paragraph (3)—

19                         (A) in subparagraph (A), by inserting “a  
 20                         sole practitioner or” after “may not be”;

21                         (B) in subparagraph (B), by striking  
 22                         “such a manufacturer, supplier, or vendor” and  
 23                         inserting “a manufacturer, supplier, or vendor  
 24                         of devices of the type for which such person is  
 25                         accredited”; and

1 (C) in subparagraph (D), by striking “de-  
2 vices” and inserting “devices of the type for  
3 which such person is accredited”;

4 (3) by striking paragraph (4) (relating to selec-  
5 tion of accredited persons); and

6 (4) by redesignating paragraph (5) as para-  
7 graph (4).

8 (d) DURATION OF AUTHORITY.—Section 523(c) (21  
9 U.S.C. 360m(c)) is amended by striking “October 1,  
10 2012” and inserting “October 1, 2017”.

11 (e) REPORT.—Section 523(d) (21 U.S.C. 360m(d))  
12 is amended by striking “January 10, 2007” and inserting  
13 “January 15, 2015”.

14 **SEC. 512. PERSONS ACCREDITED TO CONDUCT INSPEC-**  
15 **TIONS.**

16 Section 704(g)(11) (21 U.S.C. 374(g)(11)) is amend-  
17 ed by striking “October 1, 2012” and inserting “October  
18 1, 2017”.



1 **TITLE VI—STRENGTHENING**  
2 **MANAGEMENT TO SUPPORT**  
3 **FDA’S PUBLIC HEALTH MIS-**  
4 **SION**

5 **SEC. 601. INTEGRATED STRATEGY AND MANAGEMENT**  
6 **PLAN.**

7 (a) STRATEGIC INTEGRATED MANAGEMENT PLAN.—

8 Not later than 1 year after the date of enactment of this  
9 Act, the Secretary shall submit to Congress a strategic  
10 integrated management plan for the Center for Drug  
11 Evaluation and Research, the Center for Biologics Evalua-  
12 tion and Research, and the Center for Devices and Radio-  
13 logical Health. Such strategic management plan shall—

14 (1) identify strategic institutional goals and pri-  
15 orities for the Center for Drug Evaluation and Re-  
16 search, the Center for Biologics Evaluation and Re-  
17 search, and the Center for Devices and Radiological  
18 Health;

19 (2) describe the actions the Secretary will take  
20 to recruit, retain, train, and continue to develop the  
21 workforce at the Center for Drug Evaluation and  
22 Research, the Center for Biologics Evaluation and  
23 Research, and the Center for Devices and Radio-  
24 logical Health to fulfill the public health mission of  
25 the Food and Drug Administration; and

1           (3) identify results-oriented, outcome-based  
2       measures that the Secretary will use to measure the  
3       progress of achieving the strategic goals and prior-  
4       ities identified under paragraph (1) and the effec-  
5       tiveness of the actions identified under paragraph  
6       (2), including metrics to ensure that managers and  
7       reviewers of the Center for Drug Evaluation and Re-  
8       search, the Center for Biologics Evaluation and Re-  
9       search, and the Center for Devices and Radiological  
10      Health are familiar with and appropriately and con-  
11      sistently apply the requirements under the Federal  
12      Food, Drug, and Cosmetic Act (21 U.S.C. 301 et  
13      seq.), including new requirements under the 2012  
14      user fee agreements.

15      (b) REPORT.—Not later than January 1, 2016, the  
16      Comptroller General of the United States shall issue a re-  
17      port regarding the strategic management plan described  
18      in subsection (a) and related actions carried out by the  
19      Food and Drug Administration. Such report shall—

20           (1) assess the effectiveness of the actions de-  
21      scribed in paragraph (2) in recruiting, retaining,  
22      training, and developing the workforce at the Center  
23      for Drug Evaluation and Research, the Center for  
24      Biologics Evaluation and Research, and the Center  
25      for Devices and Radiological Health in fulfilling the

1 public health mission of the Food and Drug Admin-  
2 istration;

3 (2) assess the effectiveness of the measures  
4 identified under paragraph (2) in gauging progress  
5 against the strategic goals and priorities identified  
6 under paragraph (1);

7 (3) assess the extent to which the Center for  
8 Drug Evaluation and Research, the Center for Bio-  
9 logics Evaluation and Research, and the Center for  
10 Devices and Radiological Health are using the iden-  
11 tified results-oriented set of performance measures  
12 in tracking their workload by strategic goals and the  
13 effectiveness of such measures;

14 (4) assess the extent to which performance in-  
15 formation is collected, analyzed, and acted on by  
16 managers; and

17 (5) make recommendations, as appropriate, re-  
18 garding how the strategic management plan and re-  
19 lated actions of the Center for Drug Evaluation and  
20 Research, the Center for Biologics Evaluation and  
21 Research, and the Center for Devices and Radio-  
22 logical Health could be improved to fulfill the public  
23 health mission of the Food and Drug Administration  
24 in as efficient and effective manner as possible.

1 **SEC. 602. INDEPENDENT ASSESSMENT.**

2 (a) IN GENERAL.—The Secretary shall contract with  
3 a private, independent consulting firm capable of per-  
4 forming the technical analysis, management assessment,  
5 and program evaluation tasks required to conduct a com-  
6 prehensive assessment of the process for the review of  
7 drug applications under subsections (b) and (j) of section  
8 505 of the Federal Food, Drug, and Cosmetic Act (21  
9 U.S.C. 355(b), (j)) and subsections (a) and (k) of section  
10 351 of the Public Health Service Act (42 U.S.C. 262(a),  
11 (k)). The assessment shall address the premarket review  
12 process of drugs by the Food and Drug Administration,  
13 using an assessment framework that draws from appro-  
14 priate quality system standards, including management  
15 responsibility, documents controls and records manage-  
16 ment, and corrective and preventive action.

17 (b) PARTICIPATION.—Representatives of the Food  
18 and Drug Administration and manufacturers of drugs  
19 subject to user fees under part 2 of subchapter C of chap-  
20 ter VII of the Federal Food, Drug, and Cosmetic Act (21  
21 U.S.C. 379g et seq.) shall participate in a comprehensive  
22 assessment of the process for the review of drug applica-  
23 tions under section 505 of the Federal Food, Drug, and  
24 Cosmetic Act and section 351 of the Public Health Service  
25 Act. The assessment shall be conducted in phases.

1       (c) FIRST CONTRACT.—The Secretary shall award  
2 the contract for the first assessment under this section  
3 not later than March 31, 2013. Such contractor shall  
4 evaluate the implementation of recommendations and pub-  
5 lish a written assessment not later than February 1, 2016.

6       (d) FINDINGS AND RECOMMENDATIONS.—

7           (1) IN GENERAL.—The Secretary shall publish  
8 the findings and recommendations under this section  
9 that are likely to have a significant impact on review  
10 times not later than 6 months after the contract is  
11 awarded. Final comprehensive findings and rec-  
12 ommendations shall be published not later than 1  
13 year after the contract is awarded.

14          (2) IMPLEMENTATION PLAN.—The Food and  
15 Drug Administration shall publish an implementa-  
16 tion plan not later than 6 months after the date of  
17 receipt of each set of recommendation.

18       (e) SCOPE OF ASSESSMENT.—The assessment under  
19 this section shall include the following:

20           (1) Identification of process improvements and  
21 best practices for conducting predictable, efficient,  
22 and consistent premarket reviews that meet regu-  
23 latory review standards.

1           (2) Analysis of elements of the review process  
2           that consume or save time to facilitate a more effi-  
3           cient process. Such analysis shall include—

4                   (A) consideration of root causes for ineffi-  
5                   ciencies that may affect review performance and  
6                   total time to decision;

7                   (B) recommended actions to correct any  
8                   failures to meet user fee program goals; and

9                   (C) consideration of the impact of com-  
10                  bination products on the review process.

11           (3) Assessment of methods and controls of the  
12           Food and Drug Administration for collecting and re-  
13           porting information on premarket review process re-  
14           source use and performance.

15           (4) Assessment of effectiveness of the reviewer  
16           training program of the Food and Drug Administra-  
17           tion.

18           (5) Recommendations for ongoing periodic as-  
19           sessments and any additional, more detailed or fo-  
20           cused assessments.

21           (f) REQUIREMENTS.—The Secretary shall—

22                   (1) analyze the recommendations for improve-  
23                   ment opportunities identified in the assessment, de-  
24                   velop and implement a corrective action plan, and  
25                   ensure it effectiveness;

1           (2) incorporate the findings and recommenda-  
2           tions of the contractors, as appropriate, into the  
3           management of the premarket review program of the  
4           Food and Drug Administration; and

5           (3) incorporate the results of the assessment in  
6           a Good Review Management Practices guidance doc-  
7           ument, which shall include initial and ongoing train-  
8           ing of Food and Drug Administration staff, and  
9           periodic audits of compliance with the guidance.

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